

### **Remarks/Arguments**

Applicants have received and carefully reviewed the Final Office Action of the Examiner mailed January 6, 2012. Currently, claims 1, 27, 29-33, 40-42, 44-49, 61, and 62 remain pending of which claims 29-33 were previously withdrawn. Applicants gratefully acknowledge the Examiner's indication that claims 1, 27, and 61-62 are allowed. Claims 40-42 and 44-49 have been rejected. With this communication, claim 40 is amended to clarify relationships among the elements. No new matter is introduced. Favorable consideration of the following remarks is respectfully requested.

### **Claim Rejections – 35 USC § 102**

Claims 40-42, 44, and 46-49 were rejected under 35 U.S.C. 102(e) as anticipated by Hauser et al. (U.S. Patent No. 6,726,696), hereinafter Hauser. After careful review, Applicant must respectfully traverse this rejection.

*"A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference."*

Verdegaal Bros. v. Union Oil Co. of California, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). (See MPEP § 2131). Nowhere does Hauser appear to teach or suggest:

"a hemostatic body to seal the blood vessel puncture site; and a neck having a first side attached near a center of the flexible disk and having a second side opposite the first side attached to the hemostatic body", as recited in claim 40.

Instead, Hauser appears to teach a mechanical arterial closure device, for example device 105 of Fig. 4, "partially or completely fabricated from a biodegradable/bioabsorbable material" (col. 6, lines 13-14), which functions as a mechanical plug to close a blood vessel puncture. Hauser does not appear to disclose that the arterial closure device 105 is hemostatic by virtue of the materials from which it may be formed and indeed if it were the case that the plug material were hemostatic, that portion 140 of the plug which is disposed within the blood vessel would be expected to initiate and grow a thrombus with a significant attendant risk that the thrombus would grow to block the blood vessel in which portion 140 of the plug is deployed and/or that the

thrombus would shed with serious consequences for tissue downstream.

The Examiner appears to assume that all suitable biodegradable/bioabsorbable polymers and combinations thereof recited in the paragraph at col. 6, lines 8-25 are inherently hemostatic. Applicants respectfully disagree. Specifically with regard to collagen, Applicants note that the term “collagen” does not describe a single material, but rather the literature describes up to 16 types of collagen, some of which are characterized as nonhemostatic as, for example in the closure devices of U.S. Patent 5,192,302 to Kensey et al.:

“Irrespective of the manner by which the plug member is formed, it is preferable that at least its distally located portion is formed of a non-hemostatic material, such as polyglycolic acid, polylactide, polylactic acid, nonthrombogenic collagen, or combinations thereof.”  
(Col. 9, lines 23-28.)

In the case of the unitary plug 105 of Hauser, the entire plug including first member 140, second member 145, connecting member 150, and extending member 155 appears to be made of a single material. If the plug 105 is made of collagen rather than one of the other suitable materials, some of which also appear to be nonhemostatic, it does not appear inherently to be the case that the collagen is hemostatic in other than in the mechanical blockage sense upon which Hauser relies.

The current rejection depends upon the assumption that at least second member 145 inherently is hemostatic, a property not disclosed by Hauser. In the absence of an inherently hemostatic plug 105, Hauser does not appear to disclose, explicitly or inherently, each and every element set forth in independent claim 40, and Applicants respectfully request that the rejection of claim 40 be withdrawn.

Additionally, for similar reasons as well as others, claims 41, 42, 44, and 46-49, which depend from claim 40, and include significant additional limitations, are believed to be not anticipated by Hauser and Applicants respectfully request that the rejections be withdrawn.

#### **Claim Rejections – 35 USC § 103**

Claim 45 was rejected under 35 U.S.C. 103(a) as being unpatentable over Hauser in view of Brigante et al. (U.S. Published Patent Application No. 2005/0033326),

hereinafter Briganti. After careful review, Applicant must respectfully traverse this rejection.

"All words in a claim must be considered in judging the patentability of that claim against the prior art." *In re Wilson*, 424 F.2d 1382, 1385, 165 USPQ 494, 496 (CCPA 1970). (MPEP § 2143.03). As discussed previously, nowhere does Hauser appear to teach all the claim limitations of independent claim 40, as is required to establish a *prima facie* case of obviousness.

Briganti is asserted to disclose a vascular plug with a release mechanism comprising a suture looped through a resilient extension member; however independent claim 40 does not recite a release mechanism, a resilient extension member, or a suture looped therethrough as a limitation. Accordingly, the disclosure of Briganti does not appear to overcome the deficiencies of Hauser as applied to independent claim 40.

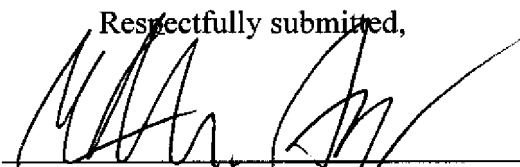
If an independent claim is nonobvious under 35 U.S.C. 103, then any claim depending therefrom is nonobvious. *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988). (MPEP 2143.03)

Accordingly, claim 45, which depends from nonobvious independent claim 40, also is believed to be nonobvious and Applicants respectfully request that the rejection be withdrawn.

In view of the foregoing, all pending claims are believed to be in a condition for allowance. Further examination is respectfully requested. Issuance of a Notice of Allowance in due course is anticipated. If a telephone conference might be of assistance, please contact the undersigned attorney at (612) 677-9050.

Respectfully submitted,

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